



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/467,903	12/21/99	HOSOKAWA	00177/522457

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EXAMINER

SCHWADRON, R

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 01/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/467,903

Applicant(s)

Hosakawa et al.

Examiner
Ron Schwadron, Ph.D.

Group Art Unit
1644



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 30-49 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 30-49 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 30-49 are under consideration.

RESPONSE TO APPLICANTS ARGUMENTS

2. The rejection of claims 30-49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,3-15 of U.S. Patent No. 5,264,221 for the reasons elaborated in the previous Office Action is withdrawn in view of the Terminal disclaimer filed 6/27/2000.

3. The rejection of claims 30-49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37,41-44,46-49,51 of copending Application No. 08450363 for the reasons elaborated in the previous Office Action is withdrawn in view of the Terminal disclaimer filed 6/27/2000.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 30-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "antibody fragment" in claims 30,35,40 or 45. The scope of the term "antibody" encompasses compositions containing antibody fragments not disclosed in the specification (eg. such as Fv or Fd or F(ab)₂

). There is no written description in the specification as originally filed of the claimed conjugate or composition containing said conjugate wherein the conjugate contains a "antibody fragment" per se. The scope of the term "antibody fragment" as recited in the claim encompasses conjugates or compositions containing said conjugates wherein antibody fragments not disclosed in the specification (eg. such as Fv or Fd or F(ab)₂) are used. There is also no support in the specification as originally filed for the recitation of "F(ab')₂" in claims 34,39,44 or 49. The specification, pages 11 and 12, discloses the use of Fab' derived from F(ab')₂ for the preparation of the claimed invention, but there is no disclosure of the use of F(ab')₂ in the claimed invention. The specification merely discloses the use of F(ab')₂ to prepare Fab', wherein the Fab' are then used in the claimed invention. Similarly, there is no disclosure in the specification as originally filed of conjugates containing "fragments thereof" or conjugates containing antibody fragments that are encompassed by said term (eg. Fd or Fv). There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter).

Regarding applicants comments in the instant amendment, the specification, pages 11 and 12, the "first method(1)" refers in the specification to a method for use in thiolation of an antibody (eg. see page 12, line 3). It does not disclose that said method is practiced with a F(ab')₂ or antibody fragment. In addition, the Traut et al. reference to which applicant refers to discloses thiolation of intact protein. Furthermore, none of the references which applicant refers to are cited in the specification. Regarding the Hosokawa et al. declaration filed 8/30/99, said declaration is not relevant to the issue under consideration. There is still no disclosure in the specification as originally filed of the scope of the claimed invention using antibody fragments per se or F(ab')₂. While such fragments and conjugates were known in the prior art, there is no disclosure in the specification as originally filed that such fragments were used in the claimed invention. There is no support in the specification as originally filed for the recitation of "antibody fragment" in claims 30,35,40 or 45.. The scope of the term "antibody fragment" encompasses compositions containing antibody fragments not disclosed in the specification (eg. such as Fv or Fd or F(ab)₂). There is no written description in the specification as originally filed of the claimed conjugate or composition containing said conjugate wherein the conjugate contains an "antibody fragment" per se. The scope of the term "antibody fragment" encompasses conjugates or compositions containing said conjugates wherein antibody fragments not disclosed in the

specification (eg. such as Fv or Fd or $F(ab)_2$) are used. The specification, pages 11 and 12, discloses the use of Fab' derived from $F(ab')_2$ for the preparation of the claimed invention, but there is no disclosure of the use of $F(ab')_2$ in the claimed invention. The specification merely discloses the use of $F(ab')_2$ to prepare Fab', wherein the Fab' are then used in the claimed invention. Similarly, there is no disclosure in the specification as originally filed of conjugates containing "antibody fragments" or conjugates containing antibody fragments that are encompassed by said term (eg. Fd or Fv). There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter). Regarding the specification, page 11, last paragraph, said passage of the specification refers to methods of conjugating an antibody to a liposome, not methods of conjugating an antibody fragment. The claimed invention is not disclosed on pages 1,3,12,36,37 or 41 of the specification. There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter). In addition, the CAFC opined in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that written description of an invention extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. The CAFC stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

3. Patentability/Validity -- Specification -- Written description (§ 115.1103)

Patent's entitlement to earlier filing date extends only to that which is disclosed in prior application, and does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed; one shows that one is "in possession" of invention of patent by describing invention, with all its claimed limitations, not that which makes it obvious, and although prior application need not describe claimed subject matter in exactly same terms used in claims, prior specification must contain equivalent description of claimed subject matter, and description which renders obvious invention for which earlier filing date is sought is not sufficient.

The CAFC also stated in Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977) that:

The invention is, for purposes of the 'written description' inquiry, whatever is now

claimed .") (emphasis in original). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used in haec verba , see Eiselstein v. Frank , 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) (" [T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims. . . ."), the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-2454.

Serial No. 09/467903
Art Unit 1644

6

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600-1600



Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644